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MEMORANDUM

September 25, 2009

BY ELECTRONIC MAIL

TO: Mr. Richard Sellers
Vice President – Feed Control and Nutrition
American Feed Industry Association

FROM: Olsson Frank Weeda Terman Bode Matz PC

RE: FDA Reportable Food Registry

The Food and Drug Administration (FDA) has issued a guidance document and other materials explaining how it intends to implement the Reportable Food Registry (RFR). These materials can be found at FDA's RFR webpage: <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>.

Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA) added a new section 417 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), requiring FDA to establish a Reportable Food Registry not later than one year after the date of enactment. Under section 417, a responsible party¹ must submit a report to FDA as soon as practicable but no later than 24 hours after the responsible party determines that an article of food it has manufactured, processed, packed, or held is a reportable food.²

¹ A “responsible party” is defined as a person who submits the FDA registration (required under FD&C Act section 415) for the food facility at which the article of food was manufactured, processed, packed, or held.

² A “reportable food” is defined as “an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences of death to humans or animals.”

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FDA is required to promptly review the information submitted by the responsible party and, if the food is a true reportable food, enter the information in the Reportable Food Registry. FDA also may direct the responsible party to notify the immediate previous sources and/or the immediate subsequent recipients of the reportable food.

Section 417 also requires that FDA establish an electronic portal which responsible parties, as well as Federal, State, and local public health officials, may use to submit reports of reportable foods to FDA. For this purpose, FDA has created the Reportable Food electronic portal, which can be accessed using the "Submit a Report" box on FDA's RFR webpage or by entering the following URL in your browser: <http://rfr.fda.gov>. If the electronic portal is not operating, look for an announcement about alternative reporting methods on FDA's website or contact your local FDA District Office. The Reportable Food electronic portal will be part of the MedWatch^{Plus} Portal, which is the electronic portal under development for reporting adverse events involving all FDA-regulated products.

FDA Implementation of the Reportable Food Registry

- Foods covered by the RFR
 - The reporting requirement applies to all FDA-regulated foods, other than infant formula and dietary supplements. This includes animal feed, pet food, and food and feed ingredients and additives.
 - It does not apply to foods regulated by the U.S. Department of Agriculture (USDA).
- The role of the responsible party
 - The obligation to report a "reportable food" belongs to the "responsible party," *i.e.*, the owner, operator, or agent in charge of the facility where the reportable food was manufactured, processed, packed, or held. This person may authorize another individual to report on its behalf. If a food is co-packed, only the owner, operator, or agent in charge of the facility that manufactured, processed, packed, or held the food is the responsible party with respect to that food. However, FDA will accept reports voluntarily submitted by other parties.
 - The responsible party must:
 - Report, via the electronic portal, as soon as possible but no later than 24 hours after determining that an article of food is a reportable food;
 - Submit supplemental or amended reports as appropriate;
 - Work with the local FDA District Office to follow up as needed;

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- Investigate the cause of the problem if the adulteration may have originated with the responsible party;
 - If instructed to do so by FDA, provide notification to all immediate previous sources and immediate subsequent recipients of the reportable food;³ and
 - Maintain records of any reports submitted or receive, and any notifications given, for 2 years and make them available to FDA upon request.
- It is up to the responsible party to determine whether an article of food is a reportable food
- The test is whether there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals.
 - FDA understands that the definition of “reportable food” involves some interpretation. Generally, the definition of a “reportable food” is similar to the definition of a Class I recall (21 C.F.R. 7.3(m)(1)), but the two are not necessarily identical.
 - Examples include: sheep feed with excessive levels of copper, swine feed with excessive levels of selenium, horse feed with excessive levels of monensin, pet food with elevated levels of melamine or cyanuric acid.
- The report must include the following data elements:
- The FDA registration numbers of the responsible party’s facilities;
 - The date on which the article of food was determined to be a reportable food;
 - A description of the reportable food, including quantity or amount;
 - The nature and extent of the adulteration;
 - The results of any investigation into the cause of the adulteration, if it may have originated with the responsible party, when known;
 - The disposition of the reportable food, when known;
 - The product information typically found on packaging, including product codes, use-by dates, and the names of the manufacturers, packers, or distributors sufficient to identify the article of food;
 - Contact information for the responsible party; and
 - Contact information for parties directly linked in the supply chain.
- A responsible party is not required to report if all of the following criteria are met:

³ The recipient of a notification should, if it meets the definition of a “responsible party,” submit its own report to FDA via the electronic portal.

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- The adulteration originated with the responsible party;
 - The responsible party detected the adulteration prior to any transfer⁴ of the reportable food to another person; and
 - The responsible party either corrected the adulteration or destroyed or caused the destruction of the reportable food.
- The reporting requirement became effective September 8, 2009, but FDA will consider exercising enforcement discretion until December 8, 2009, provided the responsible party makes a reasonable effort to comply and otherwise acts to protect public health.
- FDA's role
 - FDA will promptly review the report. If FDA determines it is a true reportable food, FDA will enter it in the RFR database. FDA may issue a press release or alert as appropriate.
 - FDA will issue a confirmation and a unique number, the Individual Case Survey Report ID (ICSR), for each instance of a reportable food to the person who submitted the report. The ICSR number must be used by the responsible party when submitting supplemental or amended reports to FDA, consulting with FDA, or providing notifications to other parties.
 - FDA will notify the appropriate FDA District Office, which will follow up with the responsible party as necessary. The role of the FDA District Office (*e.g.*, in requesting and monitoring recalls) will not change.
 - FDA will notify USDA if a USDA-regulated product may be implicated.
 - FDA will notify the Department of Homeland Security (DHS) if FDA believes the food was intentionally adulterated.
- Availability of reported information

⁴ According to FDA officials, a transfer occurs when the responsible party physically releases the food to another legal person. For example, if a reportable food is released to a third-party shipper, third-party warehouse, or customer, a transfer has occurred. However, an intra-company transfer is not a transfer.

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- The RFR (and reports submitted by responsible parties) will not be publicly available. If FDA determines that the public should be made aware of a reportable food, FDA will continue to communicate with the public as it does now (*e.g.*, via alerts, press releases). Reports will also not be viewable by any other submitters.
- Reports will be subject to Freedom of Information Act disclosure, with appropriate redactions.
- If FDA receives a report but subsequently determines that the food in question is not a reportable food, FDA will have the ability to close the report.
- Questions Remain
 - When is a food a “reportable food”?
 - A food test results in a presumptive positive for a pathogen⁵
 - A food test is positive for an indicator organism
 - A food is produced under a HACCP plan that is out of control (*e.g.*, a critical limit has been exceeded)
 - A food has pathogen contamination but will undergo further processing involving a “kill step” before it is consumed
 - When does a transfer occur for purposes of the exemption from reporting?
 - A responsible party ships a food to its customer, but the customer rejects the shipment at its loading dock
 - A responsible party ships a food to a warehouse that it leases but does not own
 - When does the 24 hour reporting deadline begin to run?
 - If a responsible party learns of a problem by receiving a notification from its supplier or customer, does the 24 hour reporting period begin to run when the

⁵ FDA’s guidance document indicates that it depends on the reliability of the testing method used. Some presumptive positives are sufficiently reliable to create a reasonable probability that the food will cause serious adverse health consequences or death to humans or animals.

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responsible party receives the notification or when the responsible party determines the food is a reportable food?⁶

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⁶ FDA's guidance document says it begins to run upon receipt of the notification. However, this appears inconsistent with the statute, which suggests it begins to run when the responsible party determines the food is a reportable food.